Office of Graduate Studies

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Responsible Conduct of Research and Graduate Education

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Today's session

- Powerpoint presentation (with audio) will be posted on Graduate Studies website under PACES menu
- Video of the session will be posted on iTunes U, accessible from Blackboard
- Please complete a program evaluation (green sheet)

Responsible Conduct of Research (RCR)

- "RCR is simply good citizenship applied to professional life." - Nicholas Steneck[1]
- Instructional areas for RCR education/training
  - Data Acquisition, Management, Sharing and Ownership
  - Conflict of Interest and Commitment
  - ***Human Subjects***
  - Animal Welfare
  - ***Research Misconduct***
  - ***Publication Practices and Responsible Authorship***
  - ***Mentor/Trainee Responsibilities***
  - Peer Review
  - Collaborative Science

[1]Steneck, NH. Introduction to the Responsible Conduct of Research. Office of Research Integrity, DHHS, 2004.

Human Subjects

- ***Research*** is defined in the federal regulations as
  - A systematic investigation (including research development, testing and evaluation), designed to develop or contribute to generalizable knowledge.

- ***Human subject*** means
  - a living individual about whom an investigator (whether professional or student) conducting research obtains: (1) Data through intervention or interaction with the individual, or; (2) Identifiable private information.

Code of Federal Regulations: 45 CFR 46.102.

Human Subjects

- Federal Wide Assurance
  - Contract between GVSU & federal government
  - Applies to all covered research activities regardless of funding source, including no funding
  - Signed by Provost

Penalties for serious or continuing violations may include suspension of all federally funded research activities at GVSU.

Human Subjects

- 3 levels of review
  - EXEMPT review: 6 defined categories.
  - EXPEDITED review: 9 defined categories.
  - FULL BOARD review: All covered research not eligible for exempt or expedited review.

Human Subjects

- EXEMPT Categories: must be minimal risk
  1. Normal educational practices
  2. Educational tests, surveys, interviews, observations (not available to studies involving *minors;* disclosure of participant identity may not increase risk)
  3. Category (2) items if not exempt but includes elected public officials (can apply to *minors)*
  4. Existing data, records, specimens if *de-identified* **or** *publicly available*
  5. Study of federal agency programs
  6. Food taste & quality evaluation

Human Subjects

- EXPEDITED categories: must be minimal risk
  1. Studies where IND/IDE application not required
  2. Blood samples (if healthy, non-preg, weight is>110 lbs)
  3. Non-invasive biological specimen collection
  4. Non-invasive biodata collection (excludes x-rays)
  5. Data previously collected for non-research purposes
  6. Audio/video recordings (some may be exempt)
  7. Non-exempt surveys, interviews (esp. w/minors)
  8. Continuing review of Full Board protocols if closed, no accrual, or data analysis only
  9. Continuing review of minimal risk full board study where #'s 2-8 do not apply (e.g. dominant hand juggling study)

Human Subjects

- FULL BOARD REVIEW
  - All studies not eligible for exempt or expedited review
  - All studies involving greater than minimal risk
  - May include life-threatening risk research studies (e.g., medical interventions, social studies interventions, etc.
  - Most studies involving protected vulnerable populations
    - Pregnant women (subpart B)
    - Prisoners in prison (subpart C)
    - Minors (<18 years) (subpart D)
    - Cognitively Impaired persons (non-regulatory protections)

Human Subjects

Authorization to conduct research at GVSU

A. Faculty investigators: unit head or designee
B. Students: research advisor authorization ***AND*** some unit heads (check !)
C. Non-GVSU collaborators: FWA # if covered by one, or Individual Investigator Agreement form

Protocols will ***NOT*** be reviewed until authorizations are recorded on IRBNet.org

Human Subjects

- Special Concerns:
  - *Data storage*: non-exempt studies must retain specific records for **6 years** if FDA regulated, or **3 years** if non-FDA. Mostly concerns signed consent forms.
  - *Data sharing*: use of cloud computing, non-GVSU collaborators, existing records, etc. require special attention to access control and use.
  - *Data security*: use of encrypted thumb drives, hard drives, and servers is ***strongly*** recommended. Password protection is not adequate.

Human Subjects

- **Review Process**
  1. Register on IRBNet.org, affiliate with GVSU
  2. **Open** a new study and **upload** all documents related to the study. Use IRBNet library to access forms. May be done piecemeal over time.
  3. **Share** study with authorizing official(s).
  4. **Submit** the study (HRRC cannot see it until submitted)
  5. Once authorized, protocol undergoes administrative review for completeness, then assigned to one (if exempt) two (if expedited) or full board of reviewers.

Human Subjects

- **Review Process**
  - HRRC chair compiles reviewer comments and issues a letter indicating the proposed research has been:
    - Determined to be not research
    - Approved
    - Disapproved (requires full board vote)
    - Tabled pending:
      - Clarifications (missing or confusing information)
      - Modifications (see specific instructions)

Response times are typically 3-4 weeks for exempt and expedited reviews, or one week following monthly full board meetings.

Human Subjects

Educational Training in Research Protections

A. Research Protections staff (331-3197; hrrc@gvsu.edu)

B. Department or classroom in-service training

C. CITI Training on-line (see link on HRRC website)

i. Social-behavioral-educational research
ii. Biomedical research
iii. Responsible conduct of research (new NSF requirement as of 1/04/10).

Human Subjects

FAQs: Audio sound & video image capturing

a. Considered personal identifiers regardless of quality
b. Images (including sketched likeness) require signed release form (e.g. NIS form)
c. Exempt review possible if identifying subjects poses no risk to subjects
d. Non-GVSU transcription of audio/video tapes requires written assurance of confidentiality
e. Consent not required if sounds/images are:
    i. in the public domain
    ii. of deceased individuals

What is Research Misconduct?

"The Fabrication, Falsification, or Plagiarism in proposing, performing or reviewing research or in reporting research results. "

OSTP Federal Policy on Research Misconduct (2005)

Research Misconduct

Fabrication is making up data or results and recording or reporting them.

42 CFR Part 93

Research Misconduct

Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

42 CFR Part 93

Research Misconduct

Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

42 CFR Part 93

Research Misconduct – Why does it happen?

Most researchers have good intentions

Pressures (including, in some cases, a lack of resources) and competition can lead to vulnerabilities in integrity.

For example:

- Deadlines and the rush to produce and publish results
- Funding and financial incentives
- Prestige and fame
- Inadequate work environments
- General frustrations and personal issues
- Fear and anxieties related to all of the above

Research Misconduct

An important aspect of integrity is how we deal with errors and mistakes.

Errors and our response to them are part of the scientific process

“The integrity of the game is everything.”

Peter Ueberroth, baseball commissioner,
May 12, 1985.

Research Misconduct

- Allegation
- Preliminary Inquiry
- Formal Inquiry
- Deciding Official
- Investigation
- Deciding Official

Research misconduct can result in a variety of actions by the government

- Debarment from federal funding or advisory relationships with federal agencies
- Involvement of other federal/local agencies (Department of Justice, etc.)
- Payment of restitution
- Retraction of publications
- Imprisonment
- When ORI reaches a conclusion of research misconduct, the findings (e.g. researcher's name) can become public

When Research Misconduct Goes Public

Illustration by
David Zinn

Research Misconduct

Research misconduct does not include honest error or differences of opinion.

42 CFR Part 93

The Grey Area of Research Malpractice

Research Misconduct

vs.

Misconduct in Research

Table 1 | Percentage of scientists who say that they engaged in the behaviour listed within the previous three years ($n = 3,247$)

Top ten behaviours	All	Mid-career	Early-career
1. Falsifying or 'cooking' research data	0.3	0.2	0.5
2. Ignoring major aspects of human-subject requirements	0.3	0.3	0.4
3. Not properly disclosing involvement in firms whose products are based on one's own research	0.3	0.4	0.3
4. Relationships with students, research subjects or clients that may be interpreted as questionable	1.4	1.3	1.4
5. Using another's ideas without obtaining permission or giving due credit	1.4	1.7	1.0
6. Unauthorized use of confidential information in connection with one's own research	1.7	2.4	0.8 ***
7. Failing to present data that contradict one's own previous research	6.0	6.5	5.3
8. Circumventing certain minor aspects of human-subject requirements	7.6	9.0	6.0 **
9. Overlooking others' use of flawed data or questionable interpretation of data	12.5	12.2	12.8
10. Changing the design, methodology or results of a study in response to pressure from a funding source	15.5	20.6	9.5 ***
Other behaviours			
11. Publishing the same data or results in two or more publications	4.7	5.9	3.4 **
12. Inappropriately assigning authorship credit	10.0	12.3	7.4 ***
13. Withholding details of methodology or results in papers or proposals	10.8	12.4	8.9 **
14. Using inadequate or inappropriate research designs	13.5	14.6	12.2
15. Dropping observations or data points from analyses based on a gut feeling that they were inaccurate	15.3	14.3	16.5
16. Inadequate record keeping related to research projects	27.5	27.7	27.3

Note: significance of χ^2 tests of differences between mid- and early-career scientists are noted by ** ($P < 0.01$) and *** ($P < 0.001$).

Martinson, Nature (2005), 435, 737.

Your Turn – What do you think?

– Dr. M. is beginning his fifth year as an independent researcher. His work is going well. He has published a number of important articles and secured a large grant for future work. Based on this progress, he expects his pending promotion review to proceed without problems.

– Late one afternoon a graduate student hands Dr. M. two papers written by a senior colleague in his department. She has circled graphs in each of the papers that are clearly the same but reported as representing two different experiments. After checking the graphs carefully and reviewing the supporting data, Dr. M. agrees that something is wrong. The senior colleague, who will almost certainly be a member of his promotion review, has either made a careless mistake or falsified information in a publication.

- **What is the compliance issue in this scenario?**
- **What should Dr. M. do?**
- **Do you think this is research misconduct?**

Responsible Authorship

- Dissemination should include:
  - Full and fair description of the work undertaken
  - An accurate report of the results
  - Honest and open assessment of the findings

- Authors should describe:
  - What they did (methods)
  - What they discovered (results)
  - What they make of their discovery (discussion)

Steneck, NH. Introduction to the Responsible Conduct of Research. Office of Research Integrity, DHHS, 2004.

Who gets to be listed as an author?

- Generally limited to individuals who make significant contributions to the work…
  - Intimate involvement in the conception/design
  - Assumed responsibility for data collection and interpretation
  - Involved with drafting the publication
  - Approved the final version of the publication
- Does one have to contribute to all phases?

Your Turn – What do you think?

Julie W. just completed a successful defense of her thesis for her master's degree. One of her committee members suggests that the research should be submitted for publication. Her thesis advisor agrees and offers to work with Julie and invites another member of the committee to assist in this effort. Since Julie is unfamiliar with the process of writing for peer-reviewed publication she assumes a secondary role in writing the paper, deferring to her thesis advisor and committee member to transform the thesis into a research manuscript for submission for publication.

- **What are the authorship issues in this scenario?**
- **What should Julie W. do?**
- **What should be the order of authorship should the paper be accepted for publication?**

Order of Authorship

- Authors usually listed in order of importance
  - First author assumed to contribute the most
  - Last author assumed to contribute the least
    - Last author could be person who ‘pulled it all together’
  - If equal contributions, list authors alphabetically

- Check with guidelines for authors of the journal
  - Some journals define importance of roles and require identification of which author did what

Corresponding Author

- The primary person responsible for:
  - Accuracy of the data
  - Names listed as authors (all deserving; none neglected)
  - Approval of final draft by all authors
  - Handles all correspondence and response to inquiries
- Could be any of the listed authors (first to last)

Steneck, NH. Introduction to the Responsible Conduct of Research. Office of Research Integrity, DHHS, 2004.

Elements of a responsible publication

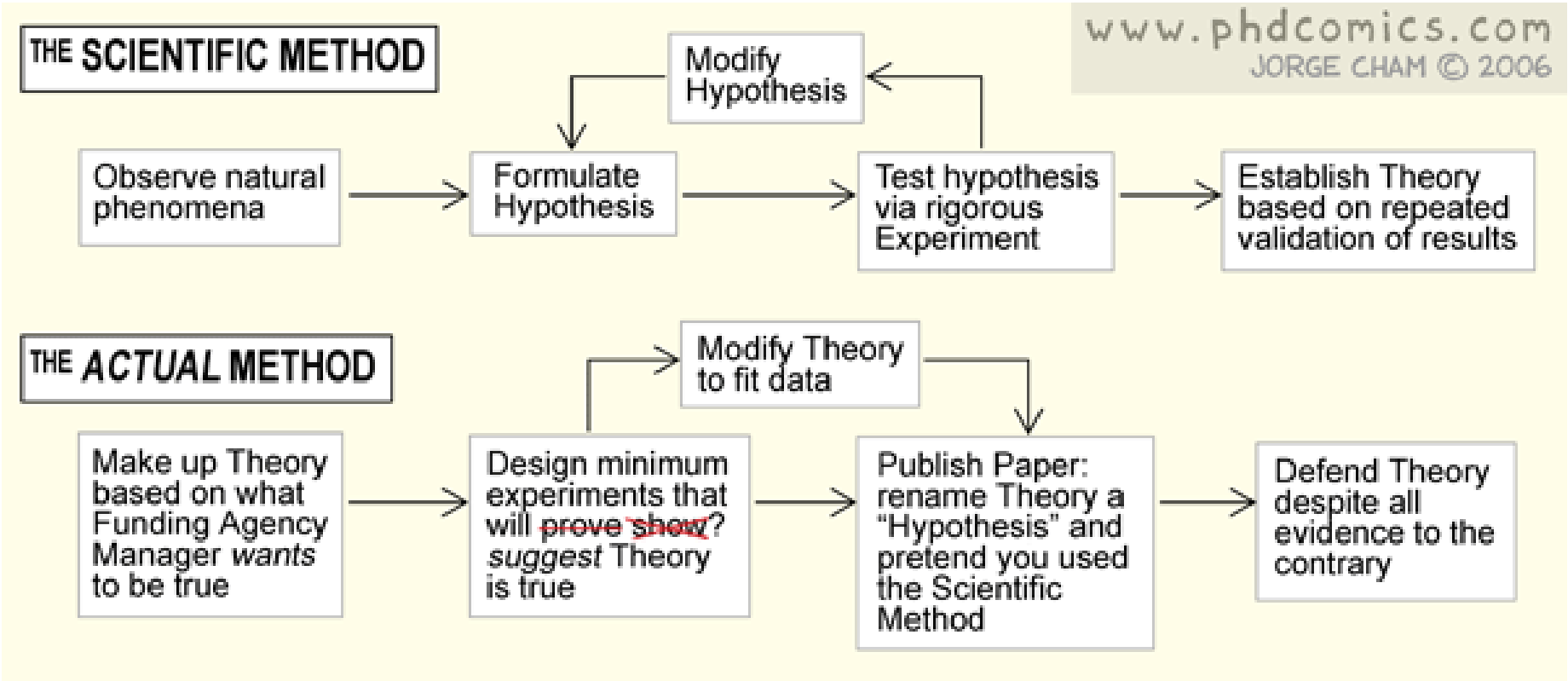
- Abstract …(it may be all anyone reads)
  - Neither overstates/understates the importance of findings
  - Data presented should be same as that in paper
  - Use of subheadings for structure

- Methods
  - Sufficient detail for replication
    - Standard methods, less description
    - New techniques, more description

Elements of a responsible publication

- Results
  - Sufficient detail to allow others to draw own conclusions
  - Don't leave out results because they disagree with the conclusions the authors would like to reach
  - A complete summary of what was discovered
- Discussion
  - Evaluation of significance of the findings… helps those less familiar with the field understand their importance
  - Provides opportunity for identifying unresolved problems and/or future research needs
  - Avoid "1-sidedness"; recognize cautions and other interpretations

How RCR can get off track…



Notes, bibliography, and acknowledgements

- Provide support for important statements of fact or assumptions
- Document the work of others used in the publication
- Point to additional reading and resources
- Recognize the support of funding agencies or colleagues and staff who do not qualify as authors

Practices to be avoided

- Honorary authorship
  - Folks who helped make it possible but did not make significant contributions
- 'Bologna' publication
  - Slicing up parts of a project for separate publications
- Duplicate publication
  - Publishing the same data more than once
- Premature public statements
  - Trumpeting research findings in the press before they have been peer-reviewed

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Responsible mentorship

- What's expected of a graduate student mentor?
  - Doing the "right" (i.e., ethically sound) thing in being fair and honest
  - Doing effective and adequate:
    - Education about standards, norms, professional behaviors
    - Research advising
    - Professional development assistance
    - Empowerment to make informed decisions
    - Modeling of ethical norms in research, practice, and higher education
  - Involves skills of empathy, collaboration, maintaining boundaries, communication, goal-setting, assessment, reflective feedback

Next PACES Event:

Finding a Research Topic & Choosing a Thesis Advisor

Faculty Panel:
Ben Lockerd, PhD (English)
Mark Staves, PhD (Biology)
Daniel Vaughn, PT, PhD (Physical Therapy)

Wed, Sept 29th 4:30 PM

University Club